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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,302	11/02/2000	Kurt Berlin	81587	4345

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EXAMINER	
SHEINBERG, MONIKA B	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/705,302	Applicant(s) BERLIN ET AL.	
	Examiner Monika B Sheinberg	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-50 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 11/20/2000 is/are: a)☐ accepted or b)☒ objected to by the Examiner. (See PTO-948)

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Drawings Notice

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached to the back of the PTO-948, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPA 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The

factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. It would constitute undue experimentation to practice the invention as claimed for the reasons set forth below.

The instant application lacks any amount or direction as to the practice of generating useful "expert rules" for disease analysis as seen in claim 1, lines 8-9 (also claims 2, 14, 16, 28, 29, and 40). The specification does not provide or suggest any rules for a disease or medical condition evaluation, particularly with respect to disease association with methylation status. The examples provided are only a generic description of the claimed method. None of the examples provide a description of what was used as the "expert rules" for evaluation and selection of a disease type or medical condition. The prior art does not teach any common rules. In addition, the applicant has defined a global problem to be solved, disease analysis for guiding the selection of therapeutic treatment regimens, but no guidance on how to implement these rules, particularly for the claimed purposes. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of detailed working examples in the specification, and the unpredictability of evaluating a disease type or medical condition, the specification, as filed is not enabling for the method of using "expert rules" for disease analysis as claimed. As such, claims drawn to the use of "expert rules" are not enabled.

The instant application lacks any amount or direction as to the practice the process of "selecting a type of disease or medical condition based on the methylation status..." as in lines 9-10 of claim 1 (also claims 14, 28 and 40). The specification does not provide or suggest any parameters within which the selection is to be practiced, nor from what list the selection is being selected from. The description does not provide or suggest the contents of the data being selected from, nor a library database in which the gathered data consists of appropriate

information sufficient for statistical purposes that would result in a meaningful and useful result. One of skill in the art would not reasonably be able to determine the parameters of the selection process based on a patient's methylation status; whether the selection must be a perfect match or if not an exact match then the thresholds for the selection are not clear or direct. The prior art does not teach any common process of disease selection. The generic examples are not actual reductions to practice for any aspect of the invention. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of detailed working examples in the specification, and the unpredictability of selecting a type of disease or medical condition, the specification, as filed is not enabling for the process of selection as claimed. As such, claims drawn to the use of the selected disease type or medical condition are not enabled.

The instant application lacks any amount or direction as to the process of generating a "ranked listing of diseases [...] based on the information about the methylation status [...]" lines 11-12 of claim 1 (also claims 14, 28 and 40). Nowhere in the claims or the specification is there a clear and direct explanation as to how the stated elements are to be ranked. The specification does not provide or suggest any parameters with which the diseases are to be ranked. The description does not provide or suggest the contents of the data on the disease being ranked, nor a library database in which the gathered data consists of appropriate information sufficient for statistical purposes that would result in a meaningful and useful result. One of skill in the art would not reasonably be able to determine the parameters of the ranked listing process based on a patient's methylation status. The prior art does not teach any common process of disease rank, particularly in association with methylation status. The generic examples are not actual reductions to practice for any aspect of the invention. While working examples are not, per se, required, the specification must provide adequate guidance such that one of skill in the art could practice the invention without undue experimentation. Given the lack of detailed working examples in the specification, and the unpredictability of ranking list of diseases, the specification, as filed is not enabling for the process of ranking a list of diseases or medical conditions based on a methylation status as claimed. As such, claims drawn to the ranked listing are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-50 are vague and indefinite in the manner of the non-sequential steps of the claims. For example claim 2 recites a third and forth knowledge base without making clear how these limitations relate to claim 1. In addition, claim 2 states a step (C) without reciting a step (A) or (B). Claim 1 appears to recite the step (A) and (B), yet it is unclear if step (C) is to occur after the third and forth knowledge, or after claim 1's step (B). The confusing steps of methodology are seen throughout the claims. The claims as a whole are structurally confusing.

Claim 1, 14, and 28 are vague and indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat App. Int. 1986). For example, claim 1 is drawn to a method for guiding the selection of a therapeutic treatment regimen for a patient, yet the claim recites a final step generating a list of diseases or medical conditions in a computing device. Claim 14 is drawn to a method of treatment, yet the nowhere in the claim is any treatment given to the patient. The claims do not set provide any final regimen selection for treatment nor an actual treatment. Claims dependent upon independent claims 1, 14 and 28 are likewise confusing.

Claims 1, 2, 14, 16, 28, 29 and 40 are vague and indefinite due to the recitation of the phrase "expert rules" lines 8 of claim 1 for example. One of skill in the art would not reasonably be able to determine the metes and bounds of "expert rules" needed for the evaluation of a disease. The following claims 3-13, 15, 17-27, 30-39 and 41-50 are also indefinite due to their dependency from the indefinite claims 1, 2, 14, 16, 28, 29 and 40.

Claim 5 and 19 are vague and indefinite due to the lack of clarity as to where the "user-defined therapeutic treatment regimen" (line 2) is being entered and by whom.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Brynjestad (US Patent 5,908,383; June 1, 1999). The reference is pertinent to the instant claims in the manner that it teaches a knowledge-based expert system that "facilitates the diagnosis and treatment" (abstract, line 3) of a medical condition such as acute and chronic pain, as recited in claim 1. The method demonstrated gathering and inputting patient and condition based information into a computer system (as seen recited in claims 1-50) that "generat[es] a treatment plan recommendation for the patient" (abstract, lines 22-24). In addition, if the original treatment, or the first ranked treatment, is "not effective initially, the treatment plan for the patient can be advanced to" (column 6, lines 45-46) the next treatment from the available options. Thus the US Patent 5,908,383 demonstrates pertinent matter to the instant invention.

Conclusion

No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 1, 2002

Monika B. Sheinberg
Art Unit 1631

MBS

Marianne P. Allen

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PRIMARY EXAMINER
GROUP 1600